

**Pre Bid Clarification of tender No. AHMS/BPL/HOSP/2019-2020/118 (General Care consumable)**

	Specification Tender Document	Vendor Quarries/Suggestuion :- Vendor 1 (M/s Arsh Traders)	Pre Bid Clarification
1	<p><b>Name of the item Technical Specification :-</b> (As per the Tender Schedule of requirement) Unit/Pack size of item (Schedule of requirement) Chapter No 04 page no 27 For <b>Item NO. 14:-</b> Sterile Latex Surgical Gloves- Non powdered (i.e. Powder free) – Disposable pair in impermeable sterile packing in Pair - Hypo allergic latex. 100% electronically tested, sterilized by Gamma Radiation / ETO of the following Sizes (in Pair)</p>	<p><b>Query :-</b> Sterile Latex Surgical Gloves- Non powdered (i.e. Powder free) – Disposable pair in impermeable sterile packing in Pair - Hypo allergic latex. 100% electronically tested, sterilized by Gamma Radiation / ETO of the following Sizes (in Pair)</p> <p><b>Suggestive remark:-</b></p> <ol style="list-style-type: none"> <li>1) Manufactured in Clean Enviornment to Comply EN 556 &amp; ISO 13485:2003</li> <li>2) Sterilized as per the validation of ISO 11135 : 2007</li> <li>3) Passes Viral penetration test ASTM F 1671 : 2007</li> <li>4) ISI marked/CE certified ( CE 0434)</li> <li>5) Each pair individually packed. Ease in donning.</li> <li>6) For Powder free glove Latex Protein less than 50 mu gram/decimeter square</li> <li>7) Length of the glove not less than 280mm From Finger to Cuff</li> <li>8) AQL of Pinhole less than 1</li> <li>9) Minimum thickness at cuff 0.14 mm</li> <li>10) Weight of pair of bare gloves should not be less than 18 gms.</li> </ol> <p><b>Justification:-</b></p> <ol style="list-style-type: none"> <li>1) EN 556 : The European Standard specifies the requirements for a terminally-sterilized medical device to be labeled "STERILE"</li> <li>2) ISO 13485 : International Standard for Medical Devices related with Quality Management systems, requirements for it's regulatory purposes. ( Simple ISO 9001 is for process not for quality )</li> <li>3) ASTM F 1671:2007 : Standard Test Method for Resistance of Pathogens. This test method is used to measure the resistance of materials used in protective Medical Devices to penetration by blood-borne pathogens using a surrogate microbe under condition of continuous blood / body fluids contact.</li> </ol>	<p><b>Clarification :-</b> Sterile Latex Surgical Gloves- Non powdered (i.e. Powder free) – Disposable pair in impermeable sterile packing in Pair - Hypo allergic latex. 100% electronically tested, sterilized by Gamma Radiation / ETO of the following Sizes (in Pair)</p> <ol style="list-style-type: none"> <li>1) Manufactured in Clean Enviornment to Comply EN 556 &amp; ISO 13485:2003</li> <li>2) Sterilized as per the validation of ISO 11135: 2007</li> <li>3) Passes Viral penetration test ASTM F 1671 : 2007</li> <li>4) ISI marked/CE certified ( CE 0434)</li> <li>5) Each pair individually packed. Ease in donning.</li> <li>6) For Powder free glove Latex Protein less than 50 mu gram/decimeter square</li> <li>7) Length of the glove not less than 280mm From Finger to Cuff</li> <li>8) AQL of Pinhole less than 1</li> <li>9) Minimum thickness at cuff 0.14 mm</li> <li>10) Weight of pair of bare gloves should not be less than 18 gms.</li> </ol>

*Handwritten signatures and dates:*  
 15.06.2020  
 15/6/20

*Handwritten signatures and dates:*  
 15/6/20  
 15/6/20

		<p>4) AQL this is a quality standard set to control the 'Pin hole defects' in gloves and is based on the findings of random sampling procedures for any particular batch / lot being produced. AQL for Pinhole 1.5. But for better protection, manufacturer should assure AQL of 1 or better AQL 0.60 and rest of the specifications suggested like, minimum Thickness of latex film of glove (0.14 mm ) &amp; minimum Length of glove ( 280 mm ) &amp; minimum weight of glove ( 18 gms ) - which complying to get the better barrier properties for Latex Surgical Gloves.</p>	
2	<p><b>Name of the item Technical Specification :-</b> (As per the Tender Schedule of requirement) Unit/Pack size of item (Schedule of requirement) Chapter No 04 page no 27 For <b>Item No. 15:-</b> Non Sterile Latex Loose Gloves (Non Powder Coated i.e. Powder free) (Pack of 100 Gloves)</p>	<p><b>Query:-</b> Non Sterile Latex Loose Gloves (Non Powder Coated i.e. Powder free) (Pack of 100 Gloves)</p> <p><b>Suggestive remark:-</b> 1) AQL of Pin Hole Less then 1.5 2) CE Mark Certified 3) Length of the glove not less than 240 mm From Finger to Cuff 4) Gloves Size Mention as (SMALL, MEDIUM, LARGE)</p> <p><b>Justification:-</b> 1.)AQL this is a quality standard set to control the 'Pin hole defects' in gloves and is based on the findings of random sampling procedures for any particular batch / lot being produced. AQL for Pinhole 1.5. But for better protection, manufacturer should assure AQL of 1 or better AQL 0.60 2.)Non Steril Gloves ( Examination Gloves ) size doesn't comes in numbers it comes in . Small, Medicum, Large).</p>	<p><b>Clarification:-</b> Non Sterile Latex Loose Gloves (Non Powder Coated i.e. Powder free) (Pack of 100 Gloves:- 1) AQL of Pin Hole Less then 1.5 2) CE Mark Certified 3) Length of the glove not less than 240 mm From Finger to Cuff 4) Gloves Size Mention as (SMALL, MEDIUM, LARGE)</p> <p style="text-align: right;"><i>AS</i> 18/6/20</p> <p style="text-align: right;"><i>AS</i> 19/6/20 Rambhadr 17/6/20</p>

*B*  
17/6/20

	Vendor 2. M/s Kanam Latex Industrial PVT LTD	
<p>3 Name of the item <b>Technical Specification :-</b> (As per the Tender Schedule of requirement) Unit/Pack size of item (Schedule of requirement) Chapter No 04 page no 27 For <b>Item NO. 14:-</b> Sterile Latex Surgical Gloves- Non powdered (i.e. Powder free) – Disposable pair in impermeable sterile packing in Pair - Hypo allergic latex. 100% electronically tested, sterilized by Gamma Radiation / ETO of the following Sizes (in Pair)</p>	<p><b>Query (A) :-</b> Sterile Latex Surgical Gloves- Non powdered (i.e. Powder free) – Disposable pair in impermeable sterile packing in Pair - Hypo allergic latex. 100% electronically tested, sterilized by Gamma Radiation / ETO of the following Sizes (in Pair)</p> <p><b>Suggestive remark:-</b></p> <ol style="list-style-type: none"> <li>1) Manufactured in Clean Environment to Comply EN 556 &amp; ISO 13485:2003</li> <li>2) Sterilized as per the validation of ISO 11135 : 2007</li> <li>3) Passes Viral penetration test ASTM F 1671 : 2007</li> <li>4) ISI marked/CE certified ( CE 0434)</li> <li>5) Each pair individually packed. Ease in donning.</li> <li>6) For Powder free glove Latex Protein less than 50 mu gram/decimeter square</li> <li>7) Length of the glove not less than 280mm From Finger to Cuff</li> <li>8) AQL of Pinhole less than 1</li> <li>9) Minimum thickness at cuff 0.14 mm</li> <li>10) Weight of pair of bare gloves should not be less than 18 gms.</li> </ol> <p><b>Justification:-</b></p> <ol style="list-style-type: none"> <li>1) EN 556 : The European Standard specifies the requirements for a terminally-sterilized medical device to be labeled "STERILE"</li> <li>2) ISO 13485 : International Standard for Medical Devices related with Quality Management systems, requirements for its regulatory purposes. (Simple ISO 9001 is for process not for quality)</li> <li>3) ASTM F 1671:2007 : Standard Test Method for Resistance of Pathogens. This test method is used to measure the resistance of materials used in protective Medical Devices to penetration by blood-borne pathogens using a surrogate microbe under condition of continuous blood / body fluids contact.</li> </ol>	<p><b>Clarification:-</b> Sterile Latex Surgical Gloves- Non powdered (i.e. Powder free) – Disposable pair in impermeable sterile packing in Pair - Hypo allergic latex. 100% electronically tested, sterilized by Gamma Radiation / ETO of the following Sizes (in Pair):- )</p> <ol style="list-style-type: none"> <li>1) Manufactured in Clean Environment to Comply EN 556 &amp; ISO 13485:2003</li> <li>2) Sterilized as per the validation of ISO 11135 : 2007</li> <li>3) Passes Viral penetration test ASTM F 1671 : 2007</li> <li>4) ISI marked/CE certified ( CE 0434)</li> <li>5) Each pair individually packed. Ease in donning.</li> <li>6) For Powder free glove Latex Protein less than 50 mu gram/decimeter square</li> <li>7) Length of the glove not less than 280mm From Finger to Cuff</li> <li>8) AQL of Pinhole less than 1</li> <li>9) Minimum thickness at cuff 0.14 mm</li> <li>10) Weight of pair of bare gloves should not be less than 18 gms.</li> </ol>

*Handwritten signature and date: M/6/20*

*Handwritten signature and date: 15/6/20*

*Handwritten signature and date: 17/6/20*

*Handwritten signature and date: 15/6/20*

*Handwritten signature and date: 15/06/20*

*Handwritten initials*

		4) AQL this is a quality standard set to control the ' Pin hole defects ' in gloves and is based on the findings of random sampling procedures for any particular batch / lot being produced. AQL for Pinhole 1.5. But for better protection, manufacturer should assure AQL of 1 or better AQL 0.60 and rest of the specifications suggested like, minimum Thickness of latex film of glove (0.14 mm ) & minimum Length of glove ( 280 mm ) & minimum weight of glove ( 18 gms ) - which complying to get the better barrier properties for Latex Surgical Gloves.	
24	<b>Name of the item Technical Specification :-</b> (As per the Tender Schedule of requirement) Unit/Pack size of item (Schedule of requirement) Chapter No 04 page no 27 For <b>Item No. 15</b> Non Sterile Latex Loose Gloves (Non Powder Coated i.e. Powder free) (Pack of 100 Gloves)	<b>Query: (B) -</b> Non Sterile Latex Loose Gloves (Non Powder Coated i.e. Powder free) (Pack of 100 Gloves) <b>Suggestive remark:-</b> 1) AQL of Pin Hole Less then 1.5 2) CE Mark Certified 3) Length of the glove not less than 240 mm From Finger to Cuff 4) Gloves Size Mention as (SMALL, MEDIUM, LARGE) <b>Justification:-</b> 1.)AQL this is a quality standard set to control the ' Pin hole defects ' in gloves and is based on the findings of random sampling procedures for any particular batch / lot being produced. AQL for Pinhole 1.5. But for better protection, manufacturer should assure AQL of 1 or better AQL 0.60.	<b>Clarification:-</b> Non Sterile Latex Loose Gloves (Non Powder Coated i.e. Powder free) (Pack of 100 Gloves) 1) AQL of Pin Hole Less then 1.5 2) CE Mark Certified 3) Length of the glove not less than 240 mm From Finger to Cuff 4) Gloves Size Mention as (SMALL, MEDIUM, LARGE)
		<b>Vendor 3. HMD Hindustan Syringes &amp; Medical Devices LTD</b>	
5	<b>Name of the item Technical Specification :-</b> (As per the Tender Schedule of requirement) Unit/Pack size of item (Schedule of requirement) Chapter No 04 page no 27 For <b>Item No. 12</b> (iii) Orange or Grey/Yellow	<b>Query :- A)</b> Orange or Grey/Yellow 'Tiger' Top, Should Thrombin, a rapid clot activator, for STAT serum testing— 4.8 ml <b>Suggestive remark:-</b> Orange or Grey/Yellow Top, Should Thrombin, a rapid clot activator, for STAT serum testing— 5ml <b>Justification :-</b> Tiger word is company specific ALSO type 4.8 ml is made	<b>Clarification :-</b> Orange or Grey/Yellow Should Thrombin, a rapid clot activator, for STAT serum testing— 4.8- 5 ml

15/6/20

15/6/20

Yogad  
15/6/20

15/6/20

	"Tiger" Top, Should Thrombin, a rapid clot activator, for STAT serum testing- 4.8 ml	1. By also a specific company , it should be 5ml which is universal for all companies	
6	<b>Name of the item Technical Specification :</b> (As per the Tender Schedule of requirement) Unit/Pack size of item (Schedule of requirement) Chapter No 04 page no 27 For Item No. 13 (i)	<b>Query :- B)</b> Size of 21 G (1.25" Inches) 40000 Nos <b>Suggestive remark:-</b> Size should be 21G 1" OR 1.5" , <b>Justification :-</b> No one is manufacturing 1.25" also don't have any specific usage of 1.25" ...kindly change it to 21x1" OR 1.5"	<b>Clarification :-</b> Size of 21 G or 21 G1"(1.25" Inches or 1.5" 40000 Nos
7	<b>Name of the item Technical Specification :</b> (As per the Tender Schedule of requirement) Unit/Pack size of item (Schedule of requirement) Chapter No 04 page no 27 For <b>Item No. 13 (ii)</b> Size of 22 G (1.25" Inches) 20000 nos	<b>Query :-C)</b> (ii) Size of 22 G (1.25" Inches) 22 G (1.25" Inches) 20000 nos <b>Suggestive remark:-</b> Size should be 22G 1" OR 1.5" , <b>Justification :-</b> No one is manufacturing 1.25" also don't have any specific usage of 1.25" ...kindly change it to 22X1" OR 1.5"	<b>Clarification :-</b> Size of 22 G or 22G 1" (1.25" or 1.5" Inches) 20000 nos

19/6/20

19/6/20

19/6/20

17/6/20

19/6/20

05/6/20